Docket No.

281387US0PCT

IN THE U PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Fabrizio SAMARITANI, et al.

SERIAL NO: 10/561,529

GAU:

FILED:

December 20, 2005

EXAMINER:

FOR:

FREEZE-DRIED FSH/LH FORMULATIONS

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

REFERENCES

- The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

RELATED CASES

- Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR 1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached PTO form 1449.
- A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

CERTIFICATION

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- □ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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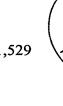
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	AA	5 384 132	01/24/95	DE MEERE et al.					
	AB	5 162 306	11/10/92	DONALDSON					
FOREIGN PATENT DOCUMENTS									
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		OTHER RE	FERENCES (Including Author, Title,	Date, Pertinent	Pages, e	tc.)		
				-administration of highly p					
	AD	gonadotrophin for the t 986 1997	gonadotrophin for the treatment of male hypogonadotropic hypogonadism", Human Reproduction, vol. 12, no. 5, pages 980- 986						
		SHOME et al. "A Reev		Amino Acid Sequence of	f Human Follitro	pin beta-S	ubunit", Jo	urnal of Protein	
	AE	Chemistry, vol. 7, no. 4, pages 325-339 1988							
	AF	KEUTMANN et al. "Structure of Human Luteinizing Hormone Beta Subunit: Evidence for a Related Carboxyl-Terminal Sequence Among Certain Peptide Hormones", Biochemical and Biophysical Research Communications, vol. 90, no. 3, pages 842-848							
			olution of the g	enes for the beta subunit	s of human chor	ionic gona	dotropin a	nd luteinizing hormone",	
	AG	Nature, vol. 307, pages 37-40 1984							
	АН	FIDDES et al. "Structure, Expression, and Evolution of the Genes for the Human Glycoprotein Hormones", Recent Progress in Hormone Research, vol. 40, pages 43-78 1984							
	Al		REICHERT et al. "Dissociation of Human Follicle-stimulating Hormone", Journal of Biological Chemistry, vol. 250, no. 8,						
		1975	alimatica and .	-harmand ramins of sin	ala abaia rasam	hinant hu	non folliala	otimulating hormone	
				pharmacodynamics of sin dotropin carboxyterminal					
	AJ	containing the human chorionic gonadotropin carboxyterminal peptide in the rhesus monkey", Fertility and Sterility, vol. 77, no. 6, pages 1248—1255							
2002 FIDDES et al. "The Gene Encoding the Common Alpha Subunit of the					nit of the Four Hu	our Human Glycoprotein Hormones" .lournal of			
	AK	FIDDES et al. "The Gene Encoding the Common Alpha Subunit of the Four Human Glycoprotein Hormones", Journal of Molecular and Applied Genetics, vol. 1, pages 3-18 1981 MALUEER et al. "Instation and Nucleatide Sequence Analysis of a Cloned aDNA Encoding the bota Subunit of Bouise."							
	AL	MAURER et al. "Isolation and Nucleotide Sequence Analysis of a Cloned cDNA Encoding the beta-Subunit of Bovine Follicle-Stimulating Hormone", DNA, vol. 5, no. 5, pages 363-369							
· · · · · · · · · · · · · · · · · · ·		1986 WATKINS et al. "DNA Sequence and Regional Assignment of the Human Follicle-Stimulating Hormone beta-Subunit Gene							
	АМ	to the Short Arm of Human Chromosome 11", DNA, vol. 6, no. 3, pages 205-212							
	AN	HIRAI et al. "The gene for the beta subunit of porcine FSH: absence of consensus oestrogen-responsive element and							
	AIN	presence of retroposons", Journal of Molecular Endocrinology, vol. 5, pages 147-158 1990							
	AO	MAURER. "Molecular Cloning and Nucleotide Sequence Analysis of Complementary Deoxyribonucleic Acid for the beta- Subunit of Rat Follide Stimulating Hormone", Molecular Endocrinology, vol. 1, pages 717-723 1987							
	AP	GUZMAN et al. "The Gene Encoding Ovine Follicle-Stimulating Hormone beta: Isolation, Characterization, and Comparison to a Related Ovine Genomic Sequence", DNA and Cell Biology, vol. 10, no. 8, pages 593-601							
	1991 KUMAR et al. "Cloning of the mouse gonadotropin beta-subunit-encoding							-	
	AQ	genes II Structure of the luteinizing hormone beta-subunit-encoding genes"						erences sheet(s) attached	
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		OTHER REFERENCES //						
	T	•	Including Author, Title, Date, Pertinent Pa					
	AR	KUMAR et al. "Cloning of the mouse gonadotropin beta-subunit-encoding genes, I. Structure of the follicle-stimulating hormone beta-subunit-encoding gene", Gene, vol. 166, pages 333-334 1995						
	AS	STEELMAN et al. "Assay of the Follicle Stimulating Hormone Based on the Augmentation with Human Chorionic Gonadotropin", Endocrinology, vol. 53, pages 604-616 1953						
	AT	VAN HELL et al. "Effects of Human Menopausal Gonadotrophin Preparations in Different Bioassay Methods", Acta Endocrinologica, vol. 47, pages 409-418 1964						
	AU							
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U.S. PCT Application Serial No: 10/561,529

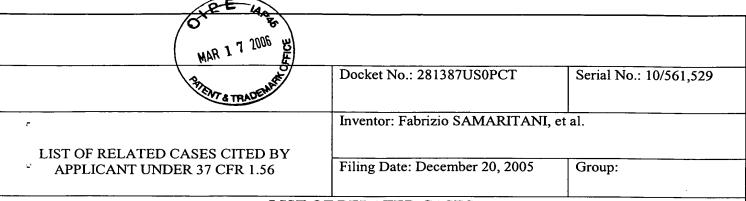
Filed: December 20, 2005 Fabrizio SAMARITANI, et al.

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STATEMENT OF RELEVANCY

- 1) References AA-AC have been cited in the International Search Report. A copy of these references is being submitted herewith.
- 2) References have been cited in the corresponding Search Report. A copy of these references is being submitted herewith.
- 3) References AD-AT are discussed in the specification. A copy of these references is being submitted herewith.
- 4) References are additional prior art known to Applicant. A copy of these references is being submitted herewith.



LIST OF RELATED CASES

Examiner <u>Initial</u>	Docket No.	Serial or <u>Patent</u> <u>Number</u>	Filing or Issue Date	Patent App. <u>Publication No.</u>	Inventor or Applicant
	281387US0PCT*	10/561,529	12/20/05		SAMARITANI, et al.
	278292US0PCT	10/551,840	10/03/05		SAMARITANI, et al.

Examiner

Date Considered